

REMARKS

This Amendment cancel claim 22, amends claim 12, adds new claim 23, amends the specification, and presents a new abstract. The correction of the  $\text{Na}_2\text{O}$  lower concentration limit to 6 wt-% in the specification, claim 12 and the abstract is supported by page 9, line 2 and page 14, line 6 of the specification as originally filed. New claim 23 is a combination of claims 12 and 22. Claims 12-21 and 23 are pending.

The U.S.C. § 103(a) rejection of claims 12, 13, 16-18, 20 and 21 over U.S. Patent No. 6,054,400 to Brink et al. is respectfully traversed. The claimed composition comprises  $\text{SiO}_2$ ,  $\text{Na}_2\text{O}$ ,  $\text{CaO}$ ,  $\text{K}_2\text{O}$ ,  $\text{MgO}$ ,  $\text{P}_2\text{O}_5$  and  $\text{B}_2\text{O}_3$ , wherein the amount of

$\text{SiO}_2$  is 51-56 wt-% of the starting oxides,

$\text{Na}_2\text{O}$  is 6-9 wt-% of the starting oxides,

$\text{CaO}$  is 21-23 wt-% of the starting oxides,

$\text{K}_2\text{O}$  is 10-12 wt-% of the starting oxides,

$\text{MgO}$  is 1-4 wt-% of the starting oxides,

$\text{P}_2\text{O}_5$  is 0.5-1.5 wt-% of the starting oxides, and

$\text{B}_2\text{O}_3$  is 0-1 wt-% of the starting oxides,

provided that the total amount of  $\text{Na}_2\text{O}$  and  $\text{K}_2\text{O}$  is 17-20 wt-% of the starting oxides.

Brink et al. discloses a bioactive glass composition in which  $\text{Na}_2\text{O}$ ,  $\text{MgO}$  and  $\text{B}_2\text{O}_3$  are optional (Col. 3, lines 24-43). None of the 40 actual compositions disclosed in Table 1 of Brink et al. disclose or suggest the claimed composition, particularly with respect to the claimed  $\text{Na}_2\text{O}$  range of 7-9 wt-%, a  $\text{CaO}$  range of 21-23 wt-% and a  $\text{P}_2\text{O}_5$  range of 0.5 to 1.5 wt-%.

The claimed composition provides unexpectedly superior resistance to crystallization after heat treatments in comparison to the closest prior art composition disclosed by Brink et al. Resistance to crystallization is important to maintaining bioactivity of the glass composition (Specification, page 1, lines 18-25).

Brink et al. discloses a "particularly preferable" bioactive glass composition consisting of

53 wt-%  $\text{SiO}_2$ ,

6 wt-%  $\text{Na}_2\text{O}$ ,

22 wt-%  $\text{CaO}$ ,

12 wt-%  $\text{K}_2\text{O}$ ,

5 wt-%  $\text{MgO}$ , and

4 wt-%  $\text{P}_2\text{O}_5$ . (Col. 4, lines 30-33). This composition is also listed in Table 1 as composition No. 27, glass 13-93, and evaluated in several of the Brink et al. examples.

The Examiner's attention is directed to Example 2 and the Comparative Example of this application, which evaluate the hydrolysis resistance of fibers prepared from an inventive composition and Brink et al.'s particularly preferable composition. As discussed therein and illustrated by Figs. 6a to 9B, fibers prepared from the claimed composition (which involved a step-wise heat treatment) and subsequently immersed in Tris for 3, 5 and 7 days exhibited a highly uniform fiber surface and uniform calcium phosphate precipitation. In contrast, different samples of fibers prepared from the comparative example's composition (corresponding to the particularly preferred composition No. 27 of Brink et al.) using the same step-wise heat treatment and immersed in Tris for 3 days exhibited different surfaces. More particularly, one fiber sample did not exhibit any calcium phosphate precipitation, in contrast to the other fiber sample, which did show calcium phosphate precipitation. This discrepancy in the comparative fiber results (which was not encountered in the inventive fibers) is believed due to partial crystallization of the Brink et al. bioactive glass during the heat treatment. See, in particular, Figs. 11A to 12B and page 15, line 32 to page 16, last line.

Composition No. 27 is the Brink et al. composition most similar to the claimed composition. Example 2 and the Comparative

Example 2 are thus persuasive evidence of the unexpected resistance to crystallization exhibited by the claimed composition. Reconsideration and withdrawal of the obviousness rejection of claims 12, 13, 16-18, 20 and 21 over Brink et al. are respectfully requested.

The 35 U.S.C. § 103(a) rejection of claims 14 and 15 over Brink et al. in view of U.S. Patent No. 5,401,693 to Bauer et al. is also traversed. As demonstrated above, the claimed composition exhibits unexpected resistance to crystallization due to heat treatment, which is detrimental to bioactivity.

Bauer et al. is cited to show bioactive glass compositions which contain  $Al_2O_3$ , which is said to increase strength and resiliency. Yet the Bauer et al. compositions are less relevant to the claimed composition than the Brink et al. composition. Moreover, there is nothing in Bauer et al. which would disclose or suggest the claimed composition would possess superior resistance to crystallization. Reconsideration and withdrawal of the obviousness rejection of claims 14 and 15 are earnestly requested.

The 35 U.S.C. § 103(a) rejection of method claims 19 and 22 over Brink et al. in view of U.S. Patent No. 3,904,425 to Young et al. is also traversed. New claim 23 expressly recites the ingredient ranges responsible for the unexpected resistance to

crystallization of the bioactive composition produced by the claimed method.

The cited combination of references fails to raise a prima facie case of obviousness against the claimed methods. The bioactive composition prepared by the method of claim 23 exhibits surprising and unexpected resistance to crystallization in comparison to the closest prior art composition of Brink et al.

Young et al. is cited to show a method of producing glasses which includes melting the glass batch, fining at 1371°C for 1-3 hours and then cooling the glass to room temperature overnight. However, Young et al. is narrowly directed to a specific glass composition which does not contain  $P_2O_5$  and whose amounts of CaO and  $K_2O$  (6.5 wt-% and 6.8 wt-%, respectively) are significantly different than that required by the claimed composition (21-23 wt-% and 10-12 wt-%, respectively). There is nothing in Young et al. which would disclose or suggest the claimed composition would possess superior resistance to crystallization. Reconsideration and withdrawal of the obviousness rejection of claims 19 and 22 are earnestly requested.

It is believed this application is in condition for allowance. Reconsideration and withdrawal of all rejections of claims 12-22, and issuance of a Notice of Allowance directed to claims 12-21 and

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23, are earnestly requested. The Examiner is urged to telephone the undersigned should he believe any further action is required for allowance.

A Petition and fee for a two month Extension of Time are being submitted herewith. It is not believed any additional fee is required for entry and consideration of this Amendment. Nevertheless, the Commissioner is authorized to charge Deposit Account No. 50-1258 in the amount of any such required fee.

Respectfully submitted,

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Enclosures:  
Substitute Abstract  
Petition for Extension of Time